IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: WAVE 6 CASES ON ATTACHED EXHIBIT A	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE CERTAIN OPINIONS OF DR. JOHN WAGNER

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, John R. Wagner, M.D. ("Dr. Wagner"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. John Wagner is an Obstetrician/Gynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such.[1] Dr. Wagner's general reports set forth opinions on all liability issues with regard to the TVT and Prolift, including failure to warn and design defect, to include opinions on the material properties of polypropylene mesh. However, Dr. Wagner has no experience drafting warnings or designing mesh devices. Dr. Wagner's experience in the field of Obstetrics and Gynecology does not render all of his opinions admissible. The admission of Dr. Wagner's unfounded opinions is

[1] *See* Wave 5 TVT General Expert Report of John R. Wagner, M.D. at p. 2 (attached as Ex. B); *see also* Wave 6 Gynemesh PS, Prolift, and Prolift +M General Expert Report of John R. Wagner M.D (attached as Ex. F); *see also* Curriculum Vitae of Dr. Wagner (attached as Ex. C).

both contrary to law and presents a serious risk of confusing the issues and misleading the jury.[2] As this Court previously noted,"[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'"[3] Accordingly, Dr. Wagner should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny. Specifically, this Court should exclude Dr. Wagner's opinions regarding: (1) the adequacy of Defendants' pelvic mesh products' warnings and IFUs, including opinions regarding what risks of the devices other doctors know of; (2) testimony regarding physical properties of the mesh, including degradation, weight, porosity, and cut of the mesh; and (3) opinions regarding the safety and efficacy of the Prolift device.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the

[2] *See Westberry v. GislavedGummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.') (citing *Daubert*, 509 U.S. at 596).
[3] *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

case." Fed. R. Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with the Defendants to "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Wagner is qualified and his testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

ARGUMENT

I. Dr. Wagner's opinions on the adequacy of defendants' warnings and what other doctors know about the risks of pelvic mesh devices should be precluded pursuant to *Daubert.*

Dr. Wagner's testimony is unreliable as he admits his opinions on the adequacy of defendants' warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device. Thus, they are *ipse dixit* opinions and precluded under *Daubert*. Dr. Wagner has no independent knowledge of FDA requirements and no knowledge of industry standards. He admits he performed no independent research on standards of any kind before publishing his expert report. Finally, he attempts to shoehorn into evidence the same type of testimony by providing impermissible, speculative testimony regarding what risks he believes "all doctors" knew or did not know about the device, while

admitting he has not used any reliable methodology in arriving at that conclusion. Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

This Court is obliged to exercise a "gatekeeping" function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (*citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at *1 (4th Cir. 2001). The proponent of the testimony has the burden of proving both relevance and reliability. *Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006). While an expert who is an urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Wagner admits he does not possess the additional expertise to offer expert testimony about what an IFU should or should not include, and therefore, his testimony regarding these issues should be excluded.

Dr. Wagner specifically testified that he has never held himself out to be an IFU expert.[4] Dr. Wagner has never drafted Instructions for Use, nor is he aware of the standards or criteria needed in drafting an IFU.[5] Without any experience or knowledge of these standards, Dr. Wagner opines on the adequacy of the pelvic mesh IFUs generally, without reference to any specific iteration.[6] However, Dr. Wagner specifically testified that the opinions he has offered

[4] *See* Wagner 3/13/2017 Dep. at 105:7-10 (attached as Ex. D).
[5] *Id*. at 105:3-6, 105:11-17.
[6] *See* Ex. B.

with regard to the adequacy of Ethicon's TVT IFUs are based only on the 2015 TVT IFU.[7] Thus, Dr. Wagner's opinions on any version of the TVT IFUs outside of the 2015 IFU are pure speculation, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.[8] Such opinions also do not "fit" any case with a pre-2015 implant, as the 2015 warnings are not relevant to whether the warnings used by the implanting physician were adequate.

Not only does Dr. Wagner possess inadequate experience, training, and knowledge with regard to designing IFUs, he only relied on the 2015 IFU in formulating his opinions. Therefore, Dr. Wagner's opinions on the adequacy of Ethicon's TVT warnings are unreliable and irrelevant, and should be precluded. At a minimum, Dr. Wagner's opinions on any TVT IFU outside of the 2015 version should be precluded.

Further, with regard to the Prolift IFU, Dr. Wagner has admitted that he is not qualified to issue an opinion regarding whether the warnings in the Prolift IFU are adequate; he can only offer an opinion as to whether or not they are accurate:

> Q. Do you feel like you have an expertise enough to offer an opinion as to whether the warnings in the IFU for the Prolift in this case are adequate?
>
> A. Again, I think they - - again, **adequacy is defined by other people, not by me.** But I think from a clinical perspective that these warnings accurately warned of the potential use, the risk of the potential use of these slings. I think they were accurate and I felt they summarized the relevant risk. **Whether or not it's adequate is a function of the regulators.**[9]

Dr. Wagner states repeatedly in his report that the risks of the pelvic mesh devices are well-known to physicians, [10] and uses this as part of the basis for his opinion that the IFU's are

[7] *See* Wagner 3/13/2017 Dep. at 196:12-17. *See* Wagner 3/13/2017 Dep. at Ex. 9 (attached as Ex. E).
[8] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).
[9] *See* Ex. G., Wagner 9/25/2017 Dep. at 102:11-24 (emphasis added) .
[10] *See* Ex. F, at 34

adequate; however, Dr. Wagner has never done any kind of survey or used any kind of formal methodology to determine what physicians did or did not know with regard to the pelvic mesh devices.[11] He has never done any kind of formal analysis to determine what percentage of mesh users knew or did not know, for example, that pain or chronic pain was a potential risk of the pelvic mesh devices. He also did not determine what percentage of physicians using the mesh devices knew of the risk of pain from exposed mesh to the patient's partner.[12] Since Dr. Wagner intends to opine that the risks of the Prolift were well known to physicians, yet he cannot quantify how many physicians knew about particular risks, he cannot reliably testify as to whether the IFUs were adequate. His opinion is not grounded on any objective evidence.

Dr. Wagner's testimony on the adequacy of Defendants' warnings is based solely, and impermissibly, on his personal belief that all surgeons have reviewed and retained information that he believes they would have, or should have, seen. Federal courts have consistently held that *ipse dixit* opinions – opinions justified solely by the fact that the expert holds them – are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong."). The Fourth Circuit concurs. *See Hollsopple*, 2001 WL 208490 at *2 ("[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert."). This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D. W. Va. 2013).

[11] Ex. G at 84:11-22
[12] *Id.* at 89:1-19; 96:5-22

To be admissible, expert testimony must explain the link between the available evidence or data and the expert's opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *9 (S.D. Ind. Apr. 19, 2007) ("It is not enough for an expert to say this is my data and that is my conclusion without connecting the two."); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) ("An opinion has a significance proportioned to the sources that sustain it.").

Similarly, in this case, Dr. Wagner has testified that he is not qualified to opine on the adequacy of the warnings in the IFU, and that his opinions on what risks are well known to physicians are not based on any objective evidence or scientifically reliable methodology. Those opinions are, therefore, inadmissible under the *Daubert* line of cases.

II. Dr. Wagner's General Opinions on the Design and Material Properties of the TVT Should Be Precluded or Limited.

Dr. Wagner does not have any experience in biomaterials engineering and has never designed mesh devices; however, he arbitrarily offers opinions regarding the design and the material properties of Ethicon's TVT device.[13] Specifically, he opines that polypropylene does not undergo mechanical changes or degrade, and that the material properties of polypropylene do not have any clinical significance for patients.[14] Dr. Wagner simply does not have the requisite experience to proffer this opinion. Dr. Wagner's opinions amount to nothing more than assumptions, and therefore are unreliable under *Daubert*.[15]

[13] *See* Ex. B.
[14] *See* Ex. B; Wagner 3/13/2017 Dep. at.163:4-164:23.
[15] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

Dr. Wagner is a board certified Obstetrician/Gynecologist with a practice focused on female urology and pelvic floor medicine.[16] Dr. Wagner does not have any specialized education, training, or experience related to the design or material properties of polypropylene mesh devices.[17] In fact, Dr. Wagner does not hold himself out to be a biomedical engineer, pathologist, epidemiologist, or expert on medical device design.[18] He has never conducted bench or laboratory research on polypropylene mesh.[19] He has not examined or even ordered any particular analysis of the mesh he has explanted.[20] He has never conducted any comparison studies between different mesh designs.[21] And, he was even under the impression that the TVT mesh pore size is the same as that of the Gynemesh PS and Prolift mesh devices.[22] Furthermore, during Dr. Wagner's testimony, he clearly demonstrated that he is unaware of how the weight of pelvic mesh is measured or calculated.[23]

Dr. Wagner's testimony regarding mesh properties is also flawed, as Dr. Wagner applies no objective standard for his conclusions regarding the properties of the mesh, and he has not researched or reviewed standards in the scientific literature which do state objective standards. For example, Dr. Wagner opines that the mesh in the Prolift is low-weight, and that the weight of the mesh is 44 grams per meter squared,[24] yet he admits that he has no objective number in mind that is a cutoff for a low-weight meshes.[25] Dr. Wagner also admits that he is not aware of objective standards that define when a mesh is considered lightweight, such as those published in

[16] *See* Ex. B at 2; Ex. C.
[17] *Id;* Wagner 3/13/2017 Dep. at 143:13-16, 143:21-22, 147:9-13, 148:12-15.
[18] Wagner 3/13/2017 Dep. at 147:24-149:4 (Dr. Wagner testified that he is not an expert in the bench work of medical device design but claimed certain surgical experience).
[19] *Id*. at 143:13-16.
[20] *See Id*. at 147:9-13,
[21] *Id*. at 143:21-22, 148:12-15.
[22] *Id*. at 196:18-198-10.
[23] *See* Wagner 3/13/2017 Dep. at 65:17-67:8.
[24] Ex. F at page 12
[25] Ex. G at 49:3-9

the peer reviewed medical literature, one of which (the Cobb-Heniford study) defines lightweight mesh as being 35 grams per meter squared or less.[26] Any weight could be considered a lightweight mesh according to Dr. Wagner's definition, as he is applying no objective, measurable standard to arrive at his conclusion that a mesh is lightweight.

Essentially, Dr. Wagner has no knowledge of the scientific and material properties of the pelvic mesh devices. Despite this lack of knowledge, education, experience, and training about the design and material properties of polypropylene mesh devices, Dr. Wagner attempts to opine on design and material properties of the pelvic mesh products, including degradation, weight, porosity, and cut (laser or mechanical).[27] These opinions undoubtedly exceed the bounds of his qualifications, are based on no objective criteria, and should be precluded under *Daubert*.

III. Dr. Wagner should be precluded from giving any opinions on the safety of the Prolift product, as his opinions are not based on objective standards, and he has not disclosed the basis for his opinions.

Dr. Wagner should be precluded from offering any opinions regarding the safety of the Prolift products as he is not applying any objective standard for his conclusions, and the basis of his conclusions have not been properly disclosed to Plaintiffs. Dr. Wagner's use of mesh products, and his qualifications as a gynecologist and pelvic floor surgeon do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device—any more than a licensed driver is qualified to opine about the safety of a vehicle based on how it feels when he drives it. Dr. Wagner testified that the foundation for his opinion that the Prolift is safe and effective is his experience, his review of the literature, and "the body of medical literature that exists out there."[28] A review of the literature does not provide sufficient basis for Dr. Wagner to offer a reliable design opinion unless he can identify an appropriate standard that he

[26] *Id*. at 46:19-47:3
[27] Laser or Mechanical refers to the TVT product. *See* Ex. B; Ex. C.
[28] Ex. G at 109:3-20

applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Here, Dr. Wagner has applied no reliably objective standard for his opinions that the Prolift devices are safe and effective:

> Q. How high would the complication rate need to be on the Prolift before you decide that the complication rate was unacceptable to you?
>
> A. That's almost – **there's no rate here.** It's almost impossible to put a number like that. This isn't a number – this isn't a number thing.
>
> ******
>
> Q. So even if the complication rate were 100 percent, it could potentially be safe and effective applying your standard?
>
> A. Again, I think we're looking at the published literature, the rates of complications as we know it compared to other procedures, including non-treatment and analyzing the patient and her disease process in light of all that and providing options.
>
> Q. And there's no numerical standard you can articulate as you sit here today where you would determine the Prolift or a device like the Prolift to not be safe and effective.
>
> A. I don't think of it as a numerical standard like that.[29]

Dr. Wagner admitted that he could potentially find that a pelvic mesh device which caused complications in 100 percent of cases might still be safe and effective, and he cannot state an objective standard for his declaration that a pelvic mesh device is not safe or not effective.[30] Nowhere does Dr. Wagner or Ethicon identify any objective standard applied by Dr. Wagner, or

[29] Id. at 108:6-14; 111:24-112:18(emphasis added)
[30] *Id.*

by which Dr. Wagner's opinions on safety and efficacy can be tested or objectively evaluated. As such, he should be precluded from giving any opinions related to the adequacy of the design, safety, and efficacy of the mesh products.

Further, a major basis for his opinions on the safety of the Prolift is the peer reviewed literature, yet it is unknown what materials Dr. Wagner reviewed or did not review from his reliance list, including what medical literature he has reviewed and relied upon for his opinion that the pelvic mesh products safe and effective.[31] Further, Dr. Wagner has reviewed company documents and deposition testimony in support of his opinions, but cannot state which items that appear on his "reliance list" he actually reviewed:

> Q. As you sit here today, do you have any type of list you could provide that would give us all of the deposition testimony and internal documents that you have actually reviewed?
>
> A. That would be very hard because I believe that counsel sent me everything on this list. So it would be very hard for me to say yes, I looked at that and I didn't look at this. It's very hard for me to separate out those two.[32]

Dr. Wagner's testimony makes clear that his reliance list does not contain an accurate list of the facts or data considered by him in forming his opinions as required by F.R Civ. P 26(a)(2)(B)(ii). Dr. Wagner testified that his reliance list was put together by counsel for Defendants, and contains materials that he did not actually review.[33] This violates F.R Civ. P 26(a)(2)(B)(ii)., and leaves Plaintiffs with an incomplete understanding of the facts and materials Dr. Wagner utilized to support his opinions. Given that Dr. Wagner did not actually review or rely on any objective standard for his opinions that the Prolift is safe and effective, and given that he failed to disclose what literature and other materials he relied upon, an appropriate remedy is to disallow this opinion either under *Daubert* or as provided in Fed. R. Civ. P. 37(c)(1).

---

[31] *Id*. at 25:2-9 *See also*, Dr. Wagner's reliance list, attached as Ex. H
[32] *Id.* at 27:4-15; *See also* 25:18-27:3
[33] *Id*., *See also* 23:17-22

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from John Wagner, regarding: (1) the adequacy of Defendants' product warnings and IFUs, including opinions regarding what risks of the devices other doctors know of; (2) testimony regarding physical properties of the mesh, including degradation, weight, porosity, and cut of the mesh; and (3) opinions regarding the safety and efficacy of the Prolift device.

Dated: October 23, 2017

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 23, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com